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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,139	04/20/2004	Steven W. Andrews	17543CON2 (AP)	5372

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Robert J. Baran - T2-7H
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EXAMINER

GRAZIER, NYEEMAH

ART UNIT	PAPER NUMBER
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1626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/829,139	Applicant(s) ANDREWS ET AL.	
	Examiner Nyeemah Grazier	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 6, 8-14 and 20-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7 and 15-19 is/are rejected.
- 7) ☒ Claim(s) 2-5, 7 and 15-19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/6/04, 4/20/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION
FIRST ACTION ON THE MERITS

I. ACTION SUMMARY

Claims 1-26 are currently pending. Claims 6, 8-14, and 20-26 are withdrawn from further consideration by the Examiner because they are drawn to a non-elected invention. 37 C.F.R. § 1.142(b).

I. PRIORITY

The instant application is a Continuation of US Application 10/389,416, filed March 13, 2003, now U.S. Patent 6,747,025; which is a Continuation of US Application 10/306,975, filed November 27, 2002, which is now ABANDONED.

II. INFORMATION DISCLOSURE STATEMENT

The information disclosure statements (IDS) submitted on April 20, 2004 and July, 6, 2004 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

III. RESTRICTION/ELECTION

A. Restriction/Election: Applicant's Response

Applicant's election of claims 1-20 and provisional species election of Example 19 of Formula (III) in the response filed on November 10, 2006 is acknowledged. The applicant traverses the restriction on the grounds that the restriction is improper because examination of claims 1-20 Formulae (II) and (III) in its entirety would not impose a burden on the Examiner. (*See*, Remarks, p. 1, filed Nov. 10, 2006).

The traversal is not found persuasive because the instant application is drawn to two different generic compounds (compound of Formula II and Formula III) wherein each formulae have multiple variables that are not within the same Markush class. For example, Formula (III)

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contains a moiety -CR₅R₆-NR₃R₄ on the indole ring whereby the R₃ and R₄ may each represent radicals such as hydrocarbyls, which may be substituted by nitrogen, halogen, phosphorus, etc. These compounds would be classified in one class under the US Classification System, Class 548. On the contrary, -NR₃R₄ may form a cyclic ring which may be substituted with heteroatoms. Thus, in the second definition of R₃R₄, the compounds of Formula (III) are now classified in various classes of the US Classification System. For instance, if the cyclic ring is a piperidine ring, then the compounds may be classified in class 546; if the cyclic ring is pyrrole, then class 548, if the cyclic ring is a morpholine ring, then the compounds may be classified in class 544, etc. A classification search is essential to determine patentability of the invention. Thus, examination of the generic formulae (II) and (III) would be a great burden on the examiner.

Further, the products are distinct as indicated by the various classifications and subclassifications. Furthermore, in view of the various combinations of the variables and the meanings of the variables, the products are distinct. Additionally, because of the plethora of classes and subclasses in each of the Inventions, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Lack of restriction would impose a serious burden on the Examiner. Thus, based on the abovementioned rationale, the restriction as set forth in the instant application is proper.

In sum, Formula (III) and Formula (II) have diverse chemical structures, different chemical properties, different modes of action, and different effects and reactive conditions and is therefore recognized in the art as being distinct from one another. MPEP §§ 806.04, 808.01. Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention, i.e. they are patentable over each other. Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The rebuttable presumption, that similar chemical structures behave similarly, may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084,

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315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure. The requirement is still deemed proper and is therefore made FINAL.

B. Status of the Claims

i. Scope of the Elected Subject Matter

The scope of the instant invention is limited to Formula (III) wherein:

X is O or $C(R^2)_2$,

Y is $[C(R^2)_2]_c$;

R^3 and R^4 , together form a piperidine ring;

c is the integer 1 or 2;

Variables R^5 , R^6 , R^1 , R_a , and b have the original definition.

ii. Non-elected Subject Matter Withdrawn 37 C.F.R. §1.142(b)

The following are withdrawn and will not be examined (claims 6, 8-14, and 20):

(1) The whole of Formula (II);

(2) Formula (III) wherein:

R^3 and R^4 , together form *any* cyclic ring substituted by a heteroatom with the exception of piperidine; or wherein R^3 and R^4 each independently represent hydrogen, hydrocarbyl and substituted hydrocarbyl radicals;

IV. REJECTION(S)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(1) Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

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invention. Claim 1 in reference to "R3 and R4" the definition should be clarified because the way that the claim is currently recited, one may interpret the phrase "R3 and R4, together with the nitrogen atom may form a cyclic ring, which ring may be substituted with said heteroatoms" to mean the formed ring will be substituted with said heteroatoms, or that one or more atoms of the formed ring is substituted with a heteroatom. In the first interpretation, the ring is limited to a ring containing one heteroatom (the nitrogen). In the second interpretation, the many heterocyclic rings may be formed (e.g. morpholine).

(2) Claim 1 is also indefinite because the claim fails to distinctly and particularly point out the how many members make up the cyclic ring. Is it a 4, 5, or 6 member ring?

(3) Claim 1 is further rejected as being indefinite because each claim must stand on its own. Here, claim 1 recites the variable "e" as an integer from 2 to 5. However, Formulae (II) and (III) do not contain the variable "e."

(4) Claim 2 recites the limitation "e" in the definition for "R". There is insufficient antecedent basis for this limitation in the claim because claim 1 does not contain the variable "e."

OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 1-5, 7, 15-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of US Patent 6,699,863 B1. A rejection based on nonstatutory double patenting is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). See also M.P.E.P. § 804 (2001).

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Obvious-type nonstatutory double patenting rejection is “analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. §103” with the distinction that the double patent rejection is not considered prior art. *Id.* See also *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Thus, the analysis employed in an obviousness-type double patent rejection is consistent with a §103(a) analysis set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966).

Claims 1-5, 7, 15-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of US Patent 6,699,863 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The instant invention is drawn to the compounds of formula (III) wherein **X** is O or $C(R^2)_2$, **Y** is $[C(R^2)_2]_c$; **R³** and **R⁴**, together form a piperidine ring; **c** is the integer 1 or 2; and the variables **R⁵**, **R⁶**, **R¹**, **R_a**, and **b** have the original definition.

Determining the Scope and Contents of the Co-pending Application

Conflicting claims 1 of the ‘863 patent recites specie compounds. Namely, claim 1 recite, *inter alia*, “3-(3H-Isobenzofuran-1-ylidene)-1-piperidin-1-ylmethyl-1,3-dihydro-indol-2-one.” See, US Patent 6,699,863 B1, col. 20, ll. 37-38.

Ascertaining the Differences Between the Copending Application and the Instant Claims

The difference between the instant claims and the ‘863 patent is that the claim in the patent is a species of the compound of the invention in the instant application. Thus, the difference is in scope. Furthermore, the difference between claim 2 and claim 1 of the ‘863 patent is a substitution (“R”) which may represent methyl (i.e., R is C1 alkyl and “a” is 1). The instant claim is not patentable over claim 1 of the ‘863 patent because the substitution of a hydrogen atom for a methyl is an obvious variant where it is the only difference in the compound. See *In re Wood, Whittaker, Sterling, and Ohta*, 199 USPQ 137 (CCPA 1978)

Resolving Level of Ordinary Skill in the Pertinent Art

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The level of ordinary skill in the pertinent art is high.

Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)

The motivation to make claimed compound derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. In re Gyurik, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979). The teachings of the '863 patent would have motivated one skilled in the art to make and use in the instant compounds and compositions with the expectation that they would both have the same pharmacokinetic effect.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

V. OBJECTION(S)

Claims 1, 4, 5 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should amend said claims by deleting the non-elected subject matter.

Dependent claims 2-5, 7, 15-19 are objected to because said claims depend from a rejected/objected based claim.

VI. CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781.

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The examiner can normally be reached on Monday through Thursday and every other Friday from 8:30 a.m. - 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,



Nyeemah Grazier, Esq.

Patent Examiner, Art Unit 1626

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